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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/828,398 | 04/20/2004 | Paul E. Luner | PC25686A | 4829 |

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
GROTON, CT 06340

| EXAMINER | |
|---|---|
| AHMED, HASAN SYED | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 11/14/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/828,398 | LUNER ET AL. | |
| | Examiner | Art Unit | |
| | HASAN S. AHMED | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2-7,11-15,17 and 43-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-7,11-15,17 and 43-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

- Receipt is acknowledged of applicants': (a) amendment, remarks, and terminal disclaimers, all filed on 8 April 2008, and (b) response to restriction requirement and amendment filed on 12 August 2008.
- The 35 USC 112 rejection and restriction requirement of 14 July 2008 are hereby withdrawn in view of the remarks. The obviousness-type double patenting rejections are hereby withdrawn in view of the terminal disclaimers.

* * * * *

### *Terminal Disclaimer*

The terminal disclaimers filed on 8 April 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on U.S. applications 10/828,079 and 10/828,419 have been reviewed and is accepted. The terminal disclaimers have been recorded.

* * * * *

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-7, 11-15, 17, and 43-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerc, et al. (WO 02/072073) in view of Nagaprasad, et al. (WO 02/076376) further in view of Fox, et al. (WO 01/76566).

Kerc et al. teach a pharmaceutical composition comprising:

- atorvastatin (*see* examples 3-6);
- a solid unit dosage (*see* page 12, lines 11-15);
- a tablet or capsule (*see* page 12, line 13);
- disordered (amorphous) atorvastatin (*see* abstract; page 5, lines 12-16; tables 1 and 4; page 10, lines 8-13; and examples 1-6); and
- a diluent concentration of, *e.g.*, 49.5% (*see* Example 1 (formulation A3), page 14, comprising microcrystalline cellulose, lactose monohydrate, and carboxymethyl cellulose).

Kerc et al. explain that their composition is beneficial in providing therapeutic equivalence in the atorvastatin pharmaceutical formulation (*see* page 3, lines 17-23).

The Kerc et al. reference differs from the instant application in that it does not explicitly disclose the atorvastatin lactone concentrations of not more than about 2% of instant claim 4. However, the claimed level of atorvastatin lactone was achieved in the atorvastatin pharmaceutical composition art before the instant application was filed (*see* Fox, et al., example 4).

The processes dry-granulation disclosed in claim 1 is not essential to a determination of patentability of the composition disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the

same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

In any event, Nagaprasad, et al. teach a statin formulation produced by dry-granulation (*see* page 4, line 26). Nagaprasad explains that dry granulation is beneficial in producing statin formulations because it leads to greater stability (*see* page 4, lines 28-29).

While Kerc does not explicitly disclose the alkalizing agent concentration range of instant claim 43, Kerc recites an alkalizing agent concentration as low as 10.4% (*see* Example 1, page 14). A prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). *See* MPEP 2144.05.

While Kerc et. al. do not explicitly teach particle sizes, granulation factors, or concentrations, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine said parameters through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the

prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the claimed parameters.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a dry-granulated pharmaceutical composition comprising atorvastatin (including disordered forms of atorvastatin), low alkaline earth metal salt additive, and low atorvastatin lactone, as taught by Kerc, et al. in view of Nagaprasad, et al., further in view of Fox, et al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it results in greater therapeutic equivalence, as explained by Kerc, et al. One of ordinary skill in the art would be motivated to use a dry-granulation process because it results in greater stability, as explained by Nagaprasad.

* * * * *

***Response to Arguments***

Applicants' arguments filed on 8 April 2008 with respect to the 35 USC 103 rejection of record have been fully considered but they are not persuasive.

1. Applicants argue, "...Kerc et al teaches that atorvastatin formulations must contain substantial quantities of bases in order to both prevent the degradation and to enhance solubility." *See* remarks, page 7.

Kerc recites an alkalizing agent concentration as low as 10.4% (*see* Example 1, page 14). A prima facie case of obviousness exists where the claimed ranges and prior

art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). *See* MPEP 2144.05. Examiner respectfully submits that applicants have not shown that the properties of a formulation comprising 5% alkalizing agent would differ critically from a formulation comprising 10.4% alkalizing agent.

2. Applicants argue, "Nagaprasad states...that the formulation must contain a carrier that imparts a pH of 6.5-8." *See* remarks, page 8.

Examiner respectfully submits that the instant claims do not set any limitation on the pH of the formulation. Furthermore, the instant claims use the open transition phrase "comprising," thus, a carrier that imparts a pH of 6.5-8 is not precluded from the instant application as it is currently claimed.

3. Applicants argue, "...Claim 43 specifies that the formulation must contain at least 40 w/w% of at least one, or a combination of, the diluents specified in the claim." *See* remarks, page 8.

Examiner respectfully submits that, in at least one example, Kerc discloses a diluent concentration of 49.5% (*see* Example 1 (formulation A3), page 14, comprising microcrystalline cellulose, lactose monohydrate, and carboxymethyl cellulose).

4. Applicants argue that the instant application differs from the prior art in that it discloses a method of making by dry granulation. *See* remarks, pages 7-9.

Examiner respectfully submits that the dry-granulation process is not essential to a determination of patentability of the composition claimed because applicants recite

product-by-process claims, not process claims. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

* * * * *

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./

Examiner, Art Unit 1615

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615